

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO**

**TODD LOPEZ, As Personal Representative
of the ESTATE OF HELEN BEGAY,**

Plaintiff,

v.

Case No. CV 20-0958 JCH/LF

**LIFE CARE CENTERS OF AMERICA, INC.,
LIFE CARE CENTER OF FARMINGTON,
PHILLIP NICKSE, in his Individual and Official
Capacities, and FARMINGTON OPERATIONS, LLC,**

Defendants.

MEMORANDUM OPINION AND ORDER

Twenty-three cases were previously consolidated with this case for purposes of ruling on the following motions to remand filed in the respective cases:

1. 1:20-cv-00958-JCH-CG, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 9);
2. 1:20-cv-00961-JB-SCY, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 9);
3. 1:20-cv-00962-SCY-LF, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 9);
4. 1:20-cv-00963-LF-GJF, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 8);
5. 1:20-cv-00964-JAP-SCY, *Lopez v. Life Care Centers of America, Inc., et al.*, Motion to Remand (ECF No. 9);
6. 1:20-cv-01077-LF-SCY, *Lopez v. Life Care Centers of America, Inc., et al.*, Motion to Remand (ECF No. 6);
7. 1:20-cv-01080-KG-LF, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 6);

8. 1:20-cv-01083-KG-LF, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 6);
9. 1:20-cv-01128-LF-JFR, *Lopez v. Life Care Center of America, Inc. et al.*, Motion to Remand (ECF No. 4);
10. 1:20-cv-01129-JB-SCY, *Lopez v. Life Care Centers of America et al.*, Motion to Remand (ECF No. 3);
11. 1:20-cv-01130-KWR-LF, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 3);
12. 1:20-cv-01131-LF-JFR, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 4);
13. 1:20-cv-01132-CG-GJF, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 3);
14. 1:20-cv-01149-JHR-GJF, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 7);
15. 1:20-cv-01157-KK-JFR, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 8);
16. 1:20-cv-01158-JFR-SCY, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 9);
17. :20-cv-01159-JFR-SCY, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 7);
18. 1:20-cv-01161-KRS-SCY, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 7);
19. 1:20-cv-01188-KK-SMV, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 4);
20. 1:20-cv-01189-KK-KRS, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 4);
21. 1:20-cv-1275-JHR-KK, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 6);
22. 1:20-cv-1351-JB-LF, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 6);

23. 1:20-cv-1352-KG-SMV, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 9);

24. 1:21-cv-00042-JHR-SCY, *Lopez v. Life Care Centers of America, Inc. et al.*, Motion to Remand (ECF No. 6).

See, e.g., Lopez v. Life Care Centers of America, Inc., et al., 20-cv-00958-JH-CG, Orders to Consolidate, ECF Nos. 16, 25, and 39.¹

Each of these cases allegedly arise from deaths from COVID-19 of residents in the care facilities operated by Defendants. The basis of the respective complaints is that, despite notice of the spread of COVID-19, none of the Defendants did anything to institute an appropriate facility plan to prevent the spread, and Defendants instructed staff not to wear masks, ordered all testing swabs destroyed without being tested, failed to sterilize equipment, reused N95 masks and nursing gowns without sterilization, required staff with COVID-19 symptoms to continue to work, and later, used the same HVAC system for quarantined and non-quarantined residents. *See, e.g.*, 0958, Am. Compl. ¶¶ 11-18, ECF No. 1-1. Defendants in each of these cases removed the cases on the basis of federal question jurisdiction, asserting that the Public Readiness and Emergency Preparedness Act (“PREP Act”), 42 U.S.C. §§ 247d-6d, 247d-6e, provides an exclusive remedy for the substance of the allegations and relief sought, and thus, expressly preempts state law. *See, e.g.*, 0958, Notice of Removal ¶¶ 8-9, ECF No. 1.

In each case, the respective plaintiff filed a motion to remand, all of which are nearly identical to one another, contending that the PREP Act does not completely preempt the respective plaintiff’s state tort claims. The Court agrees that the PREP Act’s provisions creating civil enforcement remedies do not cover the allegations in these cases, and thus, Congress did not intend to permit removal of the state law claims asserted by the plaintiffs. Accordingly, the Court, having

¹ Hereinafter, the Court for ease of reference will cite to the last four digits of the case number only.

considered all the motions, responses, replies, pleadings, applicable law, and otherwise being fully informed, concludes that the motions to remand should be granted, that this Court lacks subject matter jurisdiction over the cases, and that each of these cases should be remanded to the First Judicial District Court, County of Santa Fe, State of New Mexico.²

I. FACTUAL BACKGROUND³

Defendant Life Care Centers of America, Inc., (“LCC America”) is in the business of owning, operating, managing, and/or maintaining healthcare facilities, including Life Care Center of Farmington (“LCC Farmington”),⁴ which is a wholly-owned subsidiary of LCC America and operates in Farmington, New Mexico.⁵ LCC Farmington is the alter ego of LCC America, or alternatively, they were engaged in a joint venture or enterprise in the undertaking of the LCC Farmington nursing facility.⁶ Defendant Philip Nickse is the Executive Director of LCC Farmington, and Defendant Farmington Operations, LLC, is licensed to do business for LCC Farmington.⁷ Plaintiff Todd Lopez is an attorney who was appointed personal representative of the estates of each of the residents in the above-cited cases (collectively, “the Residents”).⁸ Each of the Residents lived in LCC Farmington and died as a result of contracting COVID-19 at LCC Farmington in either April or May 2020.⁹

² Although Defendants requested oral argument, the Court denies the request because a hearing is not necessary to resolve the motions. The briefing on the motions was thorough and well done such that additional argument will not aid the Court’s resolution of the issues.

³ The pertinent allegations necessary to resolve the motions to remand in each of these cases are virtually identical. This Court has cited to the allegations primarily in the first-filed case, and although it has not given 24 cites for each factual allegation, all 24 cases contain the same cited allegations. For ease of reference, the Court will cite each case using only the last four digits of its case number, followed by the document and/or electronic filing number.

⁴ Although the caption lists one of the defendants as “Life Care Center of Farmington,” the entity’s correct name is Life Care Centers of America, Inc., Farmington Operations, LLC d/b/a/ Life Care Center of Farmington.” 0958, Defs.’ Notice 1 n.1, ECF No. 26.

⁵ *See, e.g.*, 0958, ECF No. 1-1 at 54-55 of 77.

⁶ *See, e.g.*, 0958, ECF No. 1-1 at 57-62 of 77.

⁷ *See, e.g.*, 0958, ECF No. 1-1 at 55 of 77.

⁸ *See, e.g.*, 0958, ECF No. 1-1 at 54 of 77.

⁹ *See, e.g.*, 0958, ECF No. 1-1 at 55-57 of 77; *see, e.g.*, 0964, ECF No. 1-1 at 50 of 72.

In March 2020, LCC America learned of the spread of COVID-19¹⁰ in its facilities in Kirkland, Washington, yet despite the advance notice, neither LCC America nor LCC Farmington did anything to institute an appropriate facility plan to prevent its spread.¹¹ Defendant Nickse instructed staff at a meeting not to wear face masks so as not to frighten residents.¹² Although Medical Director Jerry Monahan ordered staff to obtain COVID-19 tests, Defendant Nickse ordered all the testing swabs destroyed without testing them.¹³ After COVID-19 arrived at LLC Farmington, Defendants failed to sterilize any equipment, including stethoscopes or blood pressure monitors, and staff were required to reuse nursing gowns and wear N95 masks several days in a row without re-sterilization between shifts.¹⁴ Several staff members who exhibited COVID-19 symptoms were still required to work, and no additional staff were hired despite a shortage that resulted in staff assigned to multiple units in LCC Farmington, increasing the COVID-19 spread.¹⁵ Residents who tested positive for COVID-19 and were quarantined were put in rooms that used the same HVAC system for quarantined and non-quarantined residents.¹⁶

Plaintiffs filed wrongful death suits in the First Judicial District, Santa Fe County, New Mexico, against all Defendants for wrongful death; negligence based on *respondeat superior*; negligent hiring, retention, and supervision; negligence *per se*; violation of the Unfair Practices Act; civil conspiracy; and punitive damages.¹⁷ According to Plaintiffs, Defendants' negligence

¹⁰ Coronaviruses are a family of viruses that cause illnesses like the common cold, but in 2019, a new coronavirus was identified called SARS-CoV-2, which causes the coronavirus disease (COVID-19). See Mayo Clinic, *Coronavirus disease 2019 (COVID-19)*, <https://www.mayoclinic.org/diseases-conditions/coronavirus/symptoms-causes/syc-20479963#:~:text=In%202019%2C%20a%20new,COVID%2D19> (last visited Jan. 29, 2021). In their factual allegations, Plaintiffs do not distinguish between the coronavirus and the disease, so the Court will likewise simply refer throughout to COVID-19, as Plaintiffs do.

¹¹ See, e.g., 0958, ECF No. 1-1 at 56 of 77.

¹² See, e.g., 0958, ECF No. 1-1 at 56 of 77.

¹³ See, e.g., 0958, ECF No. 1-1 at 56 of 77.

¹⁴ See, e.g., 0958, ECF No. 1-1 at 56 of 77.

¹⁵ See, e.g., 0958, ECF No. 1-1 at 56-57 of 77.

¹⁶ See, e.g., 0958, ECF No. 1-1 at 56 of 77.

¹⁷ See, e.g., 0958, ECF No. 1-1- at 62-76 of 77.

included failing to properly assess each Resident; failing to provide a safe environment, including proper protection from COVID-19; failing to hire a sufficient number of trained and competent staff; and failing to enact proper policies and procedures to prevent the spread of COVID-19.¹⁸ They allege that Defendants' conduct was willful and/or wanton.¹⁹

Defendants filed Notices of Removal in the respective cases. According to Defendants, the allegations in the complaints present federal questions under the PREP Act because they reflect a "covered person" involved in a "recommended activity" relative to a "covered countermeasure" under the Act.²⁰ Defendants assert that the PREP Act completely preempts Plaintiffs' claims because it created an exclusive federal remedy for claims of loss arising out of, related to, or resulting from the administration or use of a covered countermeasure where the Secretary of the Department of Health and Human Services ("HHS") issues a declaration of a public health emergency, which he did for the COVID-19 outbreak.²¹

Plaintiffs filed motions to remand in their respective cases, arguing that their claims are based solely on state law. They contend the PREP Act does not apply to their cases because it only applies to the administration and use of covered countermeasures, not to cases like these that allege negligence based on the failure to use such countermeasures or failures to act in other ways not linked to covered countermeasures.

II. SUMMARY OF DECISION

Complete preemption is rare and occurs only where a plaintiff's state law claims fall within the scope of federal statutes that Congress intended completely to displace all state law on the issue and substitute a federal cause of action for the state cause of action. The Court will thus examine

¹⁸ See, e.g., 0958, ECF No. 1-1 at 62-63 of 77.

¹⁹ See, e.g., 0958, ECF No. 1-1 at 63-64, 66-68, 70-72, 74-76 of 77.

²⁰ See, e.g., 0958, ECF No. 1 at 3 of 11.

²¹ See, e.g., 0958, ECF No. 1 at 3-10 of 11.

the language of the PREP Act in detail to determine the scope of the federal remedies, focusing especially on the language of the provisions creating the federal remedies. As explained more thoroughly herein, the PREP Act provides for an “exclusive” federal cause of action and an “exclusive” administrative remedy, but the Court declines to decide whether Congress thereby intended to remove state law claims to federal court because it concludes that the claims in this case do not fall within the scope of the PREP Act’s civil enforcement scheme.

The Court reaches this conclusion after examining the statutory language of 42 U.S.C. § 247d-6e(a) and § 247d-6d(d)(1), which created the federal administrative remedy and federal cause of action for willful misconduct claims, respectively. While the PREP Act defines willful misconduct to include both acts and omissions, this opinion addresses why the exception for willful omissions only arises if the claim for loss first falls within the ambit of § 247d-6d(a) – “claims for loss caused by, arising out of, relating to, or resulting from *the administration to or the use by an individual of a covered countermeasure.*” *Id.* § 247d-6d(a)(1) (italics added). The Court then examines guidance issued by the Secretary of the HHS regarding the meaning of “administration” and the circumstances in which a covered person may be immune from suit under the PREP Act for certain failures to administer a covered countermeasure. This decision distinguishes the HHS guidance because it is limited to situations in which the failure to use a covered countermeasure in short supply is closely connected to the administration of the covered countermeasures to others with greater priority pursuant to a CDC-approved prioritization plan. The Court looks at Supreme Court authority that differentiates between the immunity provisions that permit an ordinary preemption defense and the provisions creating a federal cause of action that may invoke the complete preemption defense. Finally, the Court turns to the allegations of Plaintiffs’ complaints, setting forth its reasons for determining that the factual allegations do not involve the direct “use”

or “administration” of a covered countermeasure on any of the Plaintiffs, as required for complete preemption under the PREP Act.

III. STANDARD OF REVIEW FOR REMOVAL

“Federal courts are courts of limited jurisdiction, possessing only that power authorized by Constitution and statute.” *Gunn v. Minton*, 568 U.S. 251, 256 (2013). Congress gave federal courts removal jurisdiction over cases initially brought in state court if the federal court could have exercised original jurisdiction. *Garley v. Sandia Corp.*, 236 F.3d 1200, 1207 (10th Cir. 2001) (citing 28 U.S.C. § 1441(a)). The burden to show federal jurisdiction is on the party invoking it. *Salzer v. SSM Health Care of Oklahoma Inc.*, 762 F.3d 1130, 1134 (10th Cir. 2014). Removal statutes must be strictly construed with all doubts resolved against removal. *Fajen v. Foundation Reserve Ins. Co., Inc.*, 683 F.2d 331, 333 (10th Cir. 1982). A district court must remand a case to state court whenever the district court lacks subject matter jurisdiction over the case. *See* 28 U.S.C. § 1447(c) (“If at any time before final judgment it appears that the district court lacks subject matter jurisdiction, the case shall be remanded.”).

IV. LAW ON COMPLETE PREEMPTION

A federal district court has jurisdiction over cases in which “a federal question is presented on the face of the plaintiff’s properly pleaded complaint.” *Caterpillar Inc. v. Williams*, 482 U.S. 386, 392 (1987). Under the well-pleaded complaint rule, if the federal question does not appear on the face of the plaintiff’s complaint, there is no federal question jurisdiction. *See Garley*, 236 F.3d at 1207. In determining whether a claim arises under federal law, courts examine the well-pleaded allegations of the complaint and ignore potential defenses. *Beneficial Nat’l Bank v. Anderson*, 539 U.S. 1, 6 (2003).

Complete preemption is an exception to the well-pleaded complaint rule, in which federal preemption makes the state claim federal in character. *Salzer*, 762 F.3d at 1134. “When the federal statute completely pre-empts the state-law cause of action, a claim which comes within the scope of that action, even if pleaded in terms of state law, is in reality based on federal law.” *Anderson*, 539 U.S. at 8. *See also Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63-64 (1987) (“Congress may so completely pre-empt a particular area that any civil complaint raising this select group of claims is necessarily federal in character.”). “There are three forms of preemption that are frequently discussed in judicial decisions—express preemption, conflict preemption, and field preemption.” *Devon Energy Prod. Co., L.P. v. Mosaic Potash Carlsbad, Inc.*, 693 F.3d 1195, 1203 n.4 (10th Cir. 2012). “[F]ederal statutes can preempt state statutes either by an express statement of preemption or by implication.” *Id.* (citation omitted). While express preemption arises from explicit statutory language about preemption, implied preemption includes field preemption or conflict preemption. *Id.*

“Ordinary preemption,” the affirmative defense that state claims have been substantively displaced by federal law, does not make the case removable, even if the validity of the preemption defense is the only issue to be resolved in the case. *Id.* In contrast, “complete preemption makes a state-law claim purely a creature of federal law, and thus removable from state to federal court from the outset.” *Id.* (citations and internal quotation marks omitted). Complete preemption is a “rare doctrine” that “represents an extraordinary pre-emptive power.” *Id.* at 1204 (internal citations omitted). Complete preemption occurs where the claims fall within the scope of federal statutes that Congress intended completely to displace all state law on the issue and comprehensively to regulate the area, so that there is no room for state-law claims. *Id.* at 1205. In other words, for complete preemption to apply, “a federal law not only preempts a state law to some degree but

also substitutes a federal cause of action for the state cause of action, thereby manifesting Congress’s intent to permit removal.” *Id.* (quoting *Schmeling v. NORDAM*, 97 F.3d 1336, 1342 (10th Cir. 1996)). The Supreme Court has recognized the complete preemption doctrine in only a few instances and warned that it should not be “lightly implied.” *Id.* at 1204-05 (quoting *Bill Johnson’s Rests., Inc. v. NLRB*, 461 U.S. 731, 752 (1983) (Brennan, J., concurring)) (noting three areas are § 301 of the Labor Management Relations Act of 1947 (“LMRA”), § 502 of the Employee Retirement Income Security Act of 1974 (“ERISA”), and actions for usury against national banks).

A court analyzing whether complete preemption applies should consider two questions: (1) whether the federal regulation at issue preempts the state law relied on by the plaintiff; and (2) whether Congress intended to allow removal in such a case, as manifested by whether it provided a federal cause of action to enforce the federal regulation. *See id.* at 1205. Courts should address the second prong first for reasons of comity and prudence, because the first prong will often require a discussion of the merits of the preemption defense. *Id.* For complete preemption to apply, the federal cause of action must provide a federal remedy that vindicates “the same basic right or interest that would otherwise be vindicated under state law.” *Id.* at 1207.

V. THE PREP ACT, THE DECLARATION OF A PUBLIC HEALTH EMERGENCY REGARDING COVID-19, AND SUBSEQUENT AMENDMENTS TO THE DECLARATION

The PREP Act empowers the Secretary of HHS to declare that a disease constitutes a public health emergency and then utilize funds established by the Treasury to manage the emergency. 42 U.S.C. § 247d(a)-(b). The Act also authorizes the Secretary to “facilitate and accelerate, as applicable, advanced research and development of security countermeasures ..., qualified countermeasures ..., or qualified pandemic or epidemic products ..., that are applicable to the public health emergency or potential public health emergency....” *Id.* § 247d(b)(2)(C). The Secretary may

recommend the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures. *Id.* § 247d-6d(b)(1).

The PREP Act provides for targeted liability protections for pandemic and epidemic products and security countermeasures. *See id.* § 247d-6d. The Act’s immunity provision states:

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration [by the Secretary of a public health emergency] has been issued with respect to such countermeasure.

Id. § 247d-6d(a)(1), § 247d-6d(b).²² The scope of this immunity “applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the ... distribution, ... administration, ... or use of such countermeasure.” *Id.* § 247d-6d(a)(2)(B).

The PREP Act also contains a “Preemption of State law” provision that applies during the effective period of a Secretary’s declaration and says in relevant part:

no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that—

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the ... use, ... dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure....

Id. § 247d-6d(b)(8).

The PREP Act further provides an “Exception to immunity of covered persons” whereby “the sole exception to the immunity from suit and liability of covered persons set forth in

²² The parties do not appear to contest that each Defendant is a “covered person” within the meaning of the PREP Act, so the Court will presume they are for purposes of resolving the motions to remand.

subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct ... by such covered person.” *Id.* § 247d-6d(d)(1). Congress defined “willful misconduct” as “an act or omission that is taken-- (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.” *Id.* § 247d-6d(c)(1)(A). These federal suits must be filed only in the United States District Court for the District of Columbia. *Id.* § 247d-6d(e)(1).

The PREP Act also created a “Covered Countermeasure Process Fund,” an emergency fund established in the Treasury and funded by Congressional appropriations, “for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration.” *Id.* § 247d-6e(a). “The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 247d-6d of this title.” *Id.* § 247d-6e(d)(4).

The parties agree that the Secretary issued a declaration regarding the COVID-19 pandemic under the PREP Act. *See, e.g.*, 0958, Pl.’s Mot. to Remand, ECF No. 9 at 5 (citing *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15,198 (Mar. 10, 2020) (“the Declaration”); and Notice of Removal, ECF No. 1 at 6-9 of 11. Amendments to the Declaration added any respiratory protective devices approved by the National Institute for Occupational Safety and Health (“NIOSH”) as a covered countermeasure. *See* Dep’t of HHS, Am. to Decl. Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 21014 (April 15, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-04-15/pdf/2020->

[08040.pdf](#) (last visited Mar. 9, 2021). The Secretary further amended the Declaration on June 8, 2020 to clarify that a covered countermeasure must be a “qualified pandemic or epidemic product,” a “security countermeasure,” a drug, biological product, or device authorized for emergency use under the Federal Food, Drug, and Cosmetic Act (“FDC Act”), or a respiratory protective device approved by NIOSH; and covered countermeasures include “qualified products that limit the harm COVID-19 might otherwise cause.” *Second Am. to Decl. under the PREP Act for Medical Countermeasures against COVID-19*, 85 Fed. Reg. 35100, 35101.

The Secretary explained the reason for adding “qualified pandemic or epidemic” products as follows:

Qualified pandemic and epidemic products that limit the harm that COVID-19 might otherwise cause are those that would not have been manufactured, administered, used, designed, developed, modified, licensed, or procured but for the COVID-19 pandemic, even when the products are manufactured, administered, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure health threats or conditions other than COVID-19. For example, the COVID-19 pandemic has resulted in shortages of certain drugs and devices that the FDA has authorized. These drugs and devices may be used for COVID-19 and other health conditions. Those shortages are “harm[s] [COVID-19] might otherwise cause.” Filling those shortages caused by COVID-19 reduces the strain on the American healthcare system by mitigating the escalation of adverse health conditions from COVID-19 and non-COVID-19 causes. And mitigating that escalation conserves limited healthcare resources—from personal protective equipment to healthcare providers—which are essential in the whole-of-Nation response to the COVID-19 pandemic.

85 Fed. Reg. at 35,101-02.

On December 9, 2020, the HHS Secretary issued a Fourth Amendment to the Declaration (“Fourth Amendment”). *See Fourth Am. to the Decl. under the PREP Act for Medical Countermeasures against COVID-19 and Republication of the Decl.*, 85 Fed. Reg. 79,190. The Fourth Amendment clarifies that the Declaration must be construed in accordance with the advisory opinions on the PREP Act issued by the HHS Office of the General Counsel (“OGC”)

and it “expressly incorporates the Advisory Opinions for that purpose.” *Id.* at 79,192. It further made explicit that “there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and this Declaration’s liability protections.” *Id.* at 79,194. The Fourth Amendment explained the meaning of “administration” under the PREP Act:

physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures.

Id. at 79,197. It then offered an example of the type of situation where an injured person complains of not having been administered a covered countermeasure that may fall within the PREP Act’s liability protections:

Where there are limited Covered Countermeasures, *not* administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute “relating to ... the administration to ... an individual” under 42 U.S.C. 247d-6d. For example, consider a situation where there is only one dose of a COVID-19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID-19. In that circumstance, the failure to administer the COVID-19 vaccine to the person in a less-vulnerable population “relate[es] to ... the administration to” the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority’s directive, can fall within the PREP Act and this Declaration’s liability protections.

Id. (internal footnote omitted).

VI. ANALYSIS

Defendants argue that the PREP Act expressly preempts Plaintiffs’ claims because they relate to Defendants’ use and administration of covered countermeasures and are against covered

persons for covered losses during the declared public health emergency. While Plaintiffs counter that their claims relate to the failure to use countermeasures, not their use, Defendants assert that the allegations challenge when and how Defendants used countermeasures, and thus fall within the PREP Act. Moreover, Defendants argue that the PREP Act also covers omissions because its purpose is to encourage the efficient use of critical resources during a national health crisis when there is a threat of critical supply shortages. According to Defendants, the PREP Act “preempts state law claims and funnels all alleged injuries into a uniform federal remedial regime so that persons at every level of the health system can respond to a highly contagious, highly dangerous, and novel disease like COVID-19 without the distraction of scattered litigation.” *E.g.*, 0958, Defs.’ Resp. 8, ECF No. 13.

A. Whether Congress intended to allow removal in a case like this one, as manifested by the provision of a federal cause of action to enforce the federal regulation

A court in analyzing the meaning of a statute or regulation should first look at its “plain and unambiguous meaning,” and if the language is clear, the analysis ends. *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997). “The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.” *Id.* at 341.

In the PREP Act, Congress provided immunity under both federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if the HHS Secretary issues a declaration. 42 U.S.C. § 247d-6d(a)(1). Congress then provided an exception to that immunity, an “exclusive Federal cause of action” when a covered person’s willful misconduct causes death or serious physical injury. *Id.* § 247d-6d(d)(1). The Act provides procedures for these claims, including provisions for jurisdiction only in the United States District Court for the District

of Columbia as well as for the burden of proof, choice of law, discovery, and damages, among others. *See id.* § 247d-6d(e)(1)-(8). For injuries not falling within the willful misconduct provision but “directly caused by the administration or use of a covered countermeasure,” the eligible individual may seek compensation administratively from the Covered Countermeasure Process Fund. *See id.* § 247d-6e(a). Congress stated that the administrative remedy “shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 247d-6d of this title.” *Id.* § 247d-6e(d)(4).

Defendants argue that these provisions evince Congressional intent to remove state claims falling within their scope to federal court. Based on the PREP Act’s language that creates an “exclusive” federal cause of action and an “exclusive” administrative remedy, Congress may have intended the PREP Act to substitute a federal claim for a state claim falling within its scope. *Cf. Anderson*, 539 U.S. at 9 (explaining that if federal statute provides exclusive cause of action, then cause of action necessarily arises under federal law and the case is removable); *In re WTC Disaster Site*, 414 F.3d 352, 375 (2d Cir. 2005) (“First, it is clear from § 408's provisions that “[t]here shall exist a Federal cause of action for damages arising out of the hijacking and subsequent crashes” and that “this cause of action shall be the exclusive remedy for damages arising out of the hijacking and subsequent crashes of such flights,” ATSSSA § 408(b)(1) (emphases added), that Congress intended to preempt all state-law claims for damages arising out of the hijackings and the subsequent crashes.”). The Court, however, need not definitively decide this issue, because it finds that Defendants have not established that the first prong of the complete preemption test is met – that the claims in this case fall within the scope of the PREP Act’s civil enforcement provisions.

B. Whether the federal regulation at issue preempts the state law relied on by the Plaintiffs

The next question is whether Congress in enacting the PREP Act intended to preempt the types of state law claims asserted by the Plaintiffs. Plaintiffs say no, because the PREP Act only applies to the use or administration of covered countermeasures, not to the failure to use them or the failure to sterilize them. Relying primarily on the immunity and willful misconduct provisions of the PREP Act, Defendants contend that Plaintiffs' claims fall squarely within the scope of the PREP Act's exclusive cause of action, because Plaintiffs allege liability related to when and how Defendants used covered countermeasures and they assert Defendants' conduct was willful and/or wanton.

More specifically, Defendants point to the following allegations that they contend relate to how they administered and used countermeasures: Defendants initially ordered staff not to wear masks, *see, e.g.*, 0958, Am. Compl. ¶ 13, ECF No. 1-1; by the time COVID-19 arrived at the center, staff were required to wear N95 masks without re-sterilization between shifts and reused nursing gowns, *id.* ¶¶ 15-16; stethoscopes and blood pressure monitors were not sterilized, *id.* ¶ 15; Defendants discarded testing swabs without testing them, *id.* ¶ 14; and subsequently, Defendants quarantined those who tested positive for COVID-19 but used the same HVAC system for quarantined and non-quarantined residents, *id.* ¶ 18. Defendants characterize these allegations as how and when they used covered countermeasures, not a failure to use them.

Turning to the basis for liability in the complaints, the following allegations do not at all relate to covered countermeasures: quarantining COVID-19-positive patients in a way that the HVAC system exposed healthy residents to the virus, *see, e.g.*, 0958, Am. Compl. ¶ 18, ECF No. 1-1; requiring staff members with COVID-19 symptoms to continue working, *id.* ¶ 17; and assigning nurses to the COVID-19 unit for one day but then reassigning them to other units shortly thereafter, *id.* ¶ 20. Because these claims are not based on covered countermeasures, they retain

their state law character and the PREP Act does not preempt such claims. *Cf. Estate of Maglioli v. Andover Subacute Rehabilitation Center I*, 478 F.Supp.3d 518, 533 (D. N.J. Aug. 12, 2020) (on appeal) (“[M]any of the measures with which Defendants allegedly failed to comply were acts such as ‘social distancing, quarantining, lockdowns, and others.’ ... These are not covered ‘countermeasures’ under the PREP Act at all.”).

Other allegations more broadly relate to covered countermeasures but are based on a failure to use them, not their use: the failure to wear face masks and the failure to test swabs. *See, e.g.*, 0958, Am. Compl. ¶¶ 13-14, ECF No. 1-1. Additionally, Plaintiffs’ respective complaints allege that liability arises from the lack of sterilization of certain equipment and then re-use of said equipment – N95 masks, *id.* ¶ 16, nursing gowns, *id.*, stethoscopes, *id.* ¶ 15, and blood pressure monitors, *id.* Defendants argue that face masks, N95 respirators, COVID-19 testing kits, stethoscopes, and blood pressure monitors all fall within the definition of medical devices approved or authorized under the FDC Act that mitigate the spread of COVID-19 or constitute NIOSH-approved respirators. Plaintiffs acknowledge that N95 masks and testing kits are covered countermeasures. *See, e.g.*, 0958, Pl.’s Reply 15, ECF No. 14 (“Obviously, then, Plaintiff’s allegations concerning masks and testing kits, which *are* covered countermeasures, apply to Defendants’ *failure to use these countermeasures* in a timely manner, if [at] all.”) (emphasis in original). Nevertheless, they contend that stethoscopes and blood pressure monitors, which are basic medical tools, do not constitute “covered countermeasures” under the PREP Act.

Because the Court concludes that the claims are not completely preempted by the PREP Act for the reasons set forth below, the Court will assume, without deciding, that the devices are covered countermeasures. The Court will turn next to the state law claims based on a failure to use

covered countermeasures and then analyze the claims based on the re-use without sterilization of covered countermeasures.

1. Whether Congress intended to permit removal of state law claims based on the failure to use countermeasures

Defendants contend that the PREP Act's broad preemptive purpose includes decisions about whether to use a particular countermeasure at all. According to Defendants, this interpretation finds support in the Secretary's definition of "administration" and the provisions creating a federal cause of action that include willful acts or omissions, *see* 42 U.S.C. § 247d-6d(c)(1). Defendants assert that the inclusion of an "omission" shows Congress' intent to include not only acts but failures to act. Defendants argue that the cases upon which Plaintiffs rely should not be followed because the courts did not consider that the definition of willful misconduct includes omissions.

Both the administrative and legal remedies provided in the PREP Act require "use" or "administration" of the covered countermeasure. The express language creating the Covered Countermeasure Process Fund says it covers injuries "directly caused by the administration or use of a covered countermeasure." 42 U.S.C. § 247d-6e(a). While the willful misconduct exception to immunity includes acts and omissions, the exception only applies if the claim first falls within subsection (a). *See id.* § 247d-6d(d)(1) (creating an "Exception to immunity of covered persons" whereby "the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct ... by such covered person"). Subsection (a)'s immunity provision applies to "claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure."

Id. § 247d-6d(a)(1). The omission thus must occur within the context of using or administering a covered countermeasure for the willful misconduct federal cause of action to apply.

This interpretation finds support in the PREP Act provision detailing the procedures for the willful misconduct suit. *See id.* § 247d-6d(e). A plaintiff alleging willful misconduct must plead with particularity each element of the claim including “each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure *administered to or used by the person on whose behalf the complaint was filed.*” *Id.* § 247d-6d(e)(3)(A) (emphasis added). Consequently, “administration” or “use” of a covered countermeasure are elements in both civil enforcement measures provided in the PREP Act.

The PREP Act does not define “administration” or “use.” The common meaning of “use” is “to put into action or service: avail oneself of: employ.” *Use*, Merriam-Webster Online Dictionary, <https://www.merriam-webster.com/dictionary/use> (last visited Mar. 9, 2021). The lay definition of “administration” is “the act or process of administering something;” or the “performance of executive duties: management.” *Administration*, Merriam-Webster Online Dictionary, <https://www.merriam-webster.com/dictionary/administration> (last visited Mar. 9, 2021). To administer is “to manage or supervise the execution, use or conduct of” something. *Administer*, Merriam-Webster Online Dictionary, <https://www.merriam-webster.com/dictionary/administer> (last visited Mar. 9, 2021). In keeping with these common understandings of the terms, the Secretary in his Declaration defined “Administration of the Covered Countermeasure” as the “*physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or*

management and operation of locations for purpose of distributing and dispensing countermeasures.” Declaration, 85 Fed. Reg. at 15202 (*italics added*).

According to Defendants, decisions directly relating to the management and operation of countermeasure programs include decisions not to use a particular countermeasure. The Court, however, disagrees that the Secretary’s definition contemplates coverage for decisions not to use countermeasures unless they are closely connected with a decision to use countermeasures. The phrase “management and operation of countermeasure programs” indicates the management and operation of programs that distribute, dispense, and use countermeasures. Defendants assert that if the decision whether to use or not use a particular countermeasure is not included in the definition, there would be no need to define “administration” to mean anything other than “physical provision of the countermeasures to recipients.” Contrary to Defendants’ argument, including both the physical provision of the countermeasures and the decisions relating to the operation and oversight of programs that physically provide countermeasures provides immunity for all phases of decision-making and delivery regarding the use of covered countermeasures.

Defendants argue that this interpretation contradicts a recent HHS advisory opinion (which the HHS Secretary expressly incorporated into his Fourth Amendment to the Declaration) that they assert stands for the proposition that the PREP Act covers the failure to use a countermeasure. On October 23, 2020, the OGC for the HHS set forth an advisory opinion, which among other things, sought to clarify that a pharmacy that prioritizes the CDC-designated populations to receive the COVID-19 vaccine would be immune from suit under the PREP Act brought by a person who contracted COVID-19 after having sought, but not received, the COVID-19 vaccine because he did not have priority under CDC guidance due to the limited quantity of vaccine doses. *See* Advisory Opinion 20-04 on the PREP Act and the Secretary’s Declaration under the Act 1, 6-7

(Oct. 22, 2020, as modified on Oct. 23, 2020), ECF No. 13-1 (hereinafter “OGC Advisory Opinion”). The OGC explained that the management and operation of countermeasure programs and decisions directly relating to delivery, distribution, and dispensing of countermeasures “involve decisions regarding prioritization of populations to receive countermeasures while there are limited doses.” *Id.* at 6. Although “prioritization necessarily entails temporarily withholding limited doses from some recipients,” the pharmacy has PREP Act coverage when it administers the COVID-19 vaccine pursuant to CDC prioritization guidance. *Id.*

In so finding, the OGC explained that a New York court was wrong in concluding the opposite in *Casabianca v. Mount Sinai Medical Center*, 1014 N.Y. Slip. Op. 33583(U), 2014 WL 10413521 (N.Y. Sup. Dec. 12, 2014). *Id.* at 7. In *Casabianca*, an unpublished opinion, a provider distributed the H1N1 vaccine to certain eligible persons who received priority while there were shortages, but the decedent did not receive the vaccine because he did not fit in those categories. *Casabianca*, 2014 WL 10413521, at *1. After his death, his estate sued the provider, and the court held that PREP Act immunity did not apply because it only applies to the actual use of the vaccine for which it was intended. *Id.* at *4-5.

The OGC disagrees with the holding of *Casabianca*, because “administration” is broader than the “physical provision of a countermeasure” and encompasses “activities related to management and operation of programs and locations for providing countermeasures to recipients..., but only insofar as those activities directly relate to the countermeasure activities.” OGC Advisory Opinion 7, ECF No. 13-1. The OGC concluded that the “plain meaning of ‘management and operation of programs for providing countermeasures’ includes following CDC vaccine-prioritization guidelines.” *Id.*

The Court is not convinced the OGC Advisory Opinion conflicts with this Court’s analysis. Under the example given, the pharmacy falls within the scope of the PREP Act’s immunity provision because it was administering a countermeasure in the first place. Although the plaintiff was alleging the failure to give the vaccine to him, that action was taken pursuant to the pharmacy’s administration of the prioritization plan to give the vaccine to some, but not others. This specific example makes clear that the non-administration of a vaccine in limited supply necessarily arises from the decision to administer the vaccine to others first.

Defendants contend that is the situation here – that the PREP Act is designed to provide covered persons immunity when shortages of PPE and masks result in the need to use another, perhaps lesser, countermeasure in place of the countermeasure in short supply. Defendants point out that the United States Food and Drug Administration issued conservation strategies for use by healthcare organizations during the COVID-19 pandemic because “the need for personal protective equipment (PPE), such as surgical masks, surgical and isolation gowns, and surgical suits (scrubs), may outpace the supply available to health care organizations during the Coronavirus Disease 2019 (COVID-19) outbreak.” U.S. Food & Drug Administration, Surgical Mask and Gown Conservation Strategies – Letter to Health Care Providers, <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-health-care-providers> (last visited Mar. 9, 2021). Defendants argue that the PPE supply shortages are the type of scenario for which Congress intended the PREP Act to apply to provide protection to covered persons who failed to use covered countermeasures that were in short supply. For these reasons, Defendants argue that the PREP Act covers the failure to provide covered countermeasures, as alleged in these cases.

Plaintiffs, however, assert in their complaints that at one point in the pandemic, Defendant Nickse instructed staff not to wear face masks so as not to frighten residents. *See, e.g.*, 0958, Am. Compl. ¶ 13, ECF No. 1-1. Liability that may result from that inaction is from the failure to use and the failure to administer masks, not a prioritization plan to administer masks to some residents and not others. As alleged, this situation differs from one where Defendants administered a plan to have some staff wear masks, but not others, due to limited supply, or implemented a plan to use inferior quality masks because of a shortage. Based on the complaints in these cases, the alleged negligence arises from not wearing face masks and not testing swabs, *i.e.*, the failure to administer covered countermeasures; they do not arise from the implementation of a CDC-approved prioritization plan.

Additionally, Defendants argue that this interpretation ignores Congress' use of an expansive term by providing immunity for "all claims for loss caused by, arising out of, *relating to*, or resulting from" the administration or use of covered countermeasures. 42 U.S.C. § 247d-6d(a)(1) (emphasis added). The phrase "relates to" in a preemption clause "express[es] a broad pre-emptive purpose." *Coventry Health Care of Missouri, Inc. v. Nevils*, 137 S.Ct. 1190, 1197 (2017). "Congress characteristically employs the phrase to reach any subject that has 'a connection with, or reference to,' the topics the statute enumerates." *Id.* The PREP Act thus provides immunity for claims of loss that have a connection with or reference to the administration or use of a covered countermeasure. Although "relating to" is expansive, it still requires connection to the use or administration of a covered countermeasure. The HHS examples of immunity for the failure to distribute a scarce covered countermeasure to certain individuals are connected to the administration of a prioritization plan and protects those who implement the plan to employ countermeasures to some but not others. As at least one district court has explained, "the

Declaration's two conditions for PREP Act immunity in 'inaction claims' for *not* administering a covered countermeasure require a close causal relationship between the injurious inaction and the corresponding administration or use that caused it." *Anson v. HCP Prairie Village KS OPCO LLC*, Case No. 20-2346-DDC-JPO, 2021 WL 308156, at 9 (D. Kan. Jan. 29, 2021).

This Court finds persuasive the reasoning of *Estate of Maglioli*. In *Maglioli*, the United States District Court for the District of New Jersey remanded a negligence and wrongful death case against a nursing care facility for allegedly failing to take proper steps to protect residents from COVID-19, including providing only a limited number of masks. *See Estate of Maglioli*, 478 F.Supp.3d at 521-22. The district court reasoned:

The Act, as extended by the declarations, therefore covers the administration and distribution of products meant to curb the spread of COVID-19. It does not, by its plain terms, cover more generally the care received by patients in healthcare facilities. Suppose, for example, a facility was threatened with or subjected to an outbreak of COVID-19 and the physicians in charge made a decision to do nothing. In the broadest sense, this decision would relate to countermeasures, in the sense that it embodied a decision *not* to employ them. Assuming that such a decision lay outside the realm of reasonable medical judgments, it could give rise to a malpractice claim. And such a malpractice claim would not be preempted by the PREP Act, which is designed to protect those who employ countermeasures, not those who decline to employ them.

Id. at 531. Although *Maglioli* was decided without the benefit of the HHS Secretary's clarification in the Fourth Amendment to the Declaration, the case was not affected by that clarification because it did not involve allegations arising from a CDC-approved prioritization-of-use decision when administering covered countermeasures. Rather, *Maglioli*, like this case, is the type of inaction case that is not closely connected enough to the administration of a countermeasure plan to fall within the scope of the PREP Act's remedies. *See Lyons v. Cucumber Holdings, LLC*, Case No. CV 20-10571-JFW(JPRx), 2021 WL 364640, *4 (C.D. Cal. Feb. 3, 2021) (on appeal) ("Thus, pursuant to the HHS Secretary's December 3, 2020 Amendment, there is only immunity for

‘inaction claims’ when the failure to administer a covered countermeasure to one individual has ‘a close causal relationship’ to the administration of that covered countermeasure to another individual.”).

Defendants also rely on the OGC’s Advisory Opinion 21-01 issued on January 8, 2021, in which the OGC opined that the PREP Act is a “Complete Preemption” statute. *See* 1275, Defs.’ Ex. A, ECF No. 7-1 at 2-3 of 6. The Advisory Opinion addressed complete preemption issues arising in district courts that are trying to determine “whether the non-use of a covered countermeasure triggers the PREP Act and its complete preemption regime.” *Id.* at 3 of 6. The OGC criticized a district court opinion’s “black and white” view that the PREP Act does not cover the non-administration or non-use of a covered countermeasure because the view clashes with the language of the PREP Act that extends immunity to anything “relating to” the administration of a covered countermeasure. *Id.* at 4 of 6. The OGC explained that prioritization or purposeful allocation of a covered countermeasure, when done in accordance with a public health authority’s directive, may fall within the PREP Act and its liability protections. *Id.* It nonetheless contrasted purposeful allocation of scarce resources with the complete failure to purchase any PPE, the latter of which does not trigger the PREP Act because it was not the outcome of some form of decision-making process. *See id.* at 4-5 of 6.

The OGC’s Advisory Opinion primarily focused on the immunity provision of the PREP Act, and its broader “relating to” language, rather than the narrower willful misconduct and compensation fund provisions. The OGC did not take into consideration the significant difference between ordinary preemption defenses and complete preemption when determining whether a claim is subject to removal to federal court. *Cf. Caterpillar Inc. v. Williams*, 482 U.S. 386, 398 (1987) (“The fact that a defendant might ultimately prove that a plaintiff’s claims are pre-empted

under the NLRA does not establish that they are removable to federal court.”); *Schmeling v. NORDAM*, 97 F.3d 1336, 1339 (10th Cir. 1996) (rejecting notion that “a defendant's assertion of a defense based on federal law, such as the federal preemption of the state law on which a plaintiff's claim is based, [is] a proper basis for removal, even if both parties agree that the only issue for decision in a case is the validity of a federal preemption defense”) (internal citation omitted); *Anson*, 2021 WL 308156 at 9 (“So, the court is mindful of Secretary Azar's understanding that PREP Act immunity can cover certain inaction claims. But this case's motion requires the court to determine the scope of PREP Act's remedy—not its grant of immunity.”); *Martin v. Serrano Post Acute LLC*, CV 20-5937 DSF (SKx), 2020 WL 5422949, *2 (C.D. Cal. Sept. 10, 2020) (on appeal) (“Defendants make a lengthy argument in favor of their immunity under the PREP Act, but mere immunity against state law or preemption of state law is not the equivalent of complete preemption and does not provide removal jurisdiction.”).²³

The Supreme Court’s explanation of the differing jurisdictional outcomes in *Metropolitan Life Ins. Co. v. Taylor*, 481 U.S. 58 (1987), and *Franchise Tax Board of Cal. v. Construction Laborers Vacation Trust for Southern Cal.*, 463 U.S. 1, 25–27 (1983), is instructive on this distinction. In *Franchise Tax Board*, the Supreme Court held that federal courts had no jurisdiction to decide whether ERISA permitted state tax authorities to collect unpaid state income taxes by levying on funds held in trust for the taxpayers under an ERISA-covered vacation benefit plan. *Id.* at 3–4. Although it noted that section 502(a) of ERISA created express causes of action in favor of

²³ Defendants rely in part on *Garcia v. Welltower OpCo Group LLC*, Case No. SACV 20-02250JVS(KESx), 2021 WL 492581 (C.D. Cal. Feb. 10, 2021), which in turn relied on the January 8, 2021 OGC Advisory Opinion and its statement that the PREP Act is a complete preemption statute. *See* 0042, Defs.’ Resp. 2, ECF No. 14. For the reasons given herein, the Court respectfully disagrees with the analysis in *Garcia* and relies on the reasoning of the more numerous cases remanding similar claims. *See, e.g., Robertson v. Big Blue Healthcare, Inc.*, Case No. 2:20-cv-02561-HLT-TJJ, 2021 WL 764566, at *8-10 (D. Kan. Feb. 26, 2021) (declining to follow *Garcia* and remanding claims to state court because PREP Act is inapplicable to Plaintiff's claims where they did not allege injury caused by administration or use—or prioritization or purposeful allocation—of a covered countermeasure) (and cases cited therein).

participants, beneficiaries, and fiduciaries of ERISA-covered plans, as well as the Secretary of Labor, it did not provide a federal cause of action for state governments, and thus, ERISA did not completely preempt the State's state law claim. *See id.* at 24-26. The Supreme Court nevertheless explained that "even though the Court of Appeals may well be correct that ERISA precludes enforcement of the State's levy in the circumstances of this case, an action to enforce the levy is not itself preempted by ERISA." *Id.* at 26. The Supreme Court's focus for complete preemption purposes was on the language of the section of ERISA that created the cause of action.

In contrast, in *Metropolitan Life* the Supreme Court held that a plaintiff's state law claims to recover benefits from a covered plan were completely preempted by ERISA because they fell directly under section 502(a)(1)(B) of ERISA, which provided an exclusive federal cause of action to resolve such disputes. *Metropolitan Life*, 481 U.S. at 62-63. The Supreme Court discussed *Franchise Tax Board*, explaining that it held therein that "ERISA pre-emption, without more, does not convert a state claim into an action arising under federal law." *Id.* at 64 (citing *Franchise Tax Board*, 463 U.S. at 25-27). Instead, for complete preemption to displace state law, the claim must not only be pre-empted by ERISA but must also come within the scope of section 502(a) of ERISA. *Id.* Because Congress clearly "manifested an intent to make causes of action within the scope of the civil enforcement provisions of § 502(a) removable to federal court" and the plaintiff's claims fell within the scope of § 502(a), the Supreme Court concluded the plaintiff's claims were removable. *Id.* at 66-67. For purposes of determining federal jurisdiction, then, this Court must focus on the language of the civil enforcement provisions to determine their scope. As explained above, the language of the willful misconduct and compensation fund provisions are more limited than the broader language of the immunity and preemption provisions. While Defendants may ultimately be correct that the PREP Act provides immunity to suit in the circumstances of this case

(a decision this Court does not reach), the state law action is not itself completely preempted by the PREP Act. Issues of immunity are potential defenses that will be for the state court to decide. For example, should evidence emerge that the decision not to use N95 masks was in reality made based on a CDC-approved conservation strategy to give masks to certain individuals but not others due to scarcity, those facts may provide a federal defense to liability, but it does not establish that Congress intended to require removal of Plaintiffs' claims that allege the failure to use or administer covered countermeasures to Plaintiffs. This Court must generally consider the allegations as Plaintiffs asserted them in the complaints, not what Defendants wish them to be. *Cf. Caterpillar*, 482 U.S. at 397 (“Caterpillar does not seek to point out that the contract relied upon by respondents is in fact a collective agreement; rather it attempts to justify removal on the basis of facts not alleged in the complaint. The ‘artful pleading’ doctrine cannot be invoked in such circumstances.”).

In sum, this Court must focus on the provisions of the PREP Act creating the federal causes of action when determining whether Congress intended to create removal jurisdiction, not the immunity and preemption clauses that create federal defenses. Because the causes of action alleged in this case that arise from the failure to use masks or the failure to test swabs do not involve injuries caused by the use or administration of countermeasures to the decedents and do not involve injuries directly caused by the administration or use of a covered countermeasure, Congress did not intend to permit their removal to federal court. *Cf. Dupervil v. Alliance Health Operations, LLC*, __ F.Supp.3d __, 2021 WL 355137, *12, 16 (E.D.N.Y. Feb. 2, 2021) (on appeal) (explaining that where crux of plaintiff’s allegations were failures to separate residents, to enforce social distancing, to ensure adequate staffing levels, and to enforce mask-wearing, “failures cannot be said to be administering—or even prioritizing or purposefully allocating—” a covered

countermeasure to an individual within the meaning of the PREP Act and remanding case because claims were not completely preempted); *Estate of Smith v. Bristol at Tampa Rehabilitation and Nursing Center*, Case No. 8:20-cv-2798-T-60SPF, 2021 WL 100376, *1-2 & n.1 (M.D. Fla. Jan. 12, 2021) (remanding case alleging “numerous negligence claims against Defendant, including that it failed to follow proper infection protocols and guidelines, have proper PPE, and observe a wide range of appropriate safety precautions” because claims were not completely preempted by PREP Act, but noting that PREP Act defenses were for state court to decide).

2. Whether Congress in the PREP Act intended to permit removal of state law claims based on the failure to sterilize countermeasures prior to re-use

In addition to the aforementioned allegations, Plaintiffs’ respective complaints allege that liability arises from the lack of sterilization of certain equipment and then re-use of said equipment – N95 masks, *see, e.g.*, 0958, Am. Compl. ¶ 16, ECF No. 1-1, nursing gowns, *id.*, stethoscopes, *id.* ¶ 15, and blood pressure monitors, *id.* Defendants argue that the PREP Act broadly covers state laws that relate to the use or administration of countermeasures, and thus, it covers losses having a connection with or reference to the use, dispensing, and administration of countermeasures that were unsterilized. Plaintiffs contend that their allegations do not assert that Defendants administered or distributed countermeasures to the Residents and that those measures caused their death, as required by the enforcement provisions of the PREP Act. Defendants, however, argue that nothing in the statute or regulations limits the PREP Act to injuries caused by the direct provision of countermeasures to the allegedly injured individual. *See* 1275, Defs.’ Resp. 11, ECF No. 7.

While Defendants are correct that the immunity provision and preemption of state law provisions do not contain a requirement that the provision of countermeasures be “direct,” the “Covered Countermeasure Process Fund” does require that “covered injuries” be “*directly* caused

by the administration or use of a covered countermeasure.” 42 U.S.C. § 247d-6e(a) (emphasis added). Moreover, as discussed *supra*, an element for willful misconduct is “each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used *by the person on whose behalf the complaint was filed.*” *Id.* § 247d-6d(e)(3)(A) (emphasis added). Based on the statutory text, the civil enforcement mechanisms of the PREP Act are more limited in scope than the immunity provisions. Defendants’ reliance on HHS advisory opinions regarding immunity from suit, rather than the scope of the PREP Act’s federal claims, are thus inapposite. As explained in the preceding section, that a state law claim may be preempted because of a defense in a statute (ordinary preemption), such as the immunity provision of the PREP Act, does not mean that those state law claims are removable to federal court (complete preemption). Removal requires that the statute have transformed the state law claims into federal claims. *Cf. Caterpillar*, 482 U.S. at 398 (“The fact that a defendant might ultimately prove that a plaintiff’s claims are pre-empted under the NLRA does not establish that they are removable to federal court.”) (internal citations omitted); *Devon Energy*, 693 F.3d at 1203 n.4 (“[O]rdinary preemption may be invoked in both state and federal court as an affirmative defense to the allegations in a plaintiff’s complaint. Such a defense asserts that the state claims have been substantively displaced by federal law. Ordinary preemption does not render a state-law claim removable to federal court.”) (internal quotations and citations omitted).

The Court is not convinced that Congress in the PREP Act intended to transform state law negligence claims based on the failure to sterilize equipment prior to its use into federal claims. *Cf. Sherod v. Comprehensive Healthcare Management Servs., LLC*, 20cv1198, 2020 WL 6140474, *3-4, 7-8 (W.D. Pa. Oct. 16, 2020) (on appeal) (holding PREP Act did not completely preempt plaintiff’s claims that included failure to administer PPE, failure to provide training on proper PPE

use, failure to sanitize facility, and violation of OSHA related to use of PPE). Although Plaintiffs' respective allegations suggest that the lack of sterilization of equipment contributed to the spread of COVID-19 in the facility, the complaints do not allege that Defendants directly used or administered unsterilized countermeasures on Plaintiffs. *Cf.* 42 U.S.C. § 247d-6d(e)(3)(A) (requiring "each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure *administered to or used by the person on whose behalf the complaint was filed*") (emphasis added); 42 U.S.C. § 247d-6e(a) (compensation fund applies where the injuries were "*directly* caused by the administration or use of a covered countermeasure pursuant to such declaration") (italics added).

Defendants have not met their burden of establishing that the civil enforcement measures cover the failure to sterilize covered countermeasures within the nursing facility generally. Doubt should be resolved against removal. *Cf. Anson*, 2021 WL 308156 at *10, 13 (remanding wrongful death and negligence state law claims because plaintiff's allegations asserted none of the qualifying inactions under PREP Act described by HHS Secretary in Declaration and its amendments and plaintiff did not allege decedent's death was caused by the administration of covered countermeasures; rather, plaintiff alleged that the failure to use countermeasures caused decedent's death); *Parker v. St. Jude Operating Co., LLC*, No. 3:20-cv-01325-HZ, 2020 WL 8362407, at *1, 5-6 (D. Or. Dec. 28, 2020) (granting motion to remand negligence claims that included misuse of personal protective equipment because PREP Act did not completely preempt claims).

3. Conclusion

Plaintiffs' state law claims do not fall within the civil enforcement provisions of the PREP ACT. The PREP Act does not provide a replacement cause of action for the specific state law

claims asserted in this case, and thus, Congress did not intend such claims to be removed to federal court. The Court finds there is no federal jurisdiction over the claims in these cases.

IT IS THEREFORE ORDERED that the motions to remand listed *supra* on pages 1-3 are **GRANTED**. Separate orders remanding each of cases to the First Judicial District Court, County of Santa Fe, State of New Mexico, will be filed in the docket of each case by the assigned Judge.



SENIOR UNITED STATES DISTRICT JUDGE